

Veterinary Medicine Research and Development  
Pfizer Inc  
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Kalamazoo, MI 49001-0199  
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2640 5 JUL 2005 13:37 **Pfizer Animal Health**

15 July 2005

**John W. Hallberg, D.V.M., Ph.D.**  
Associate Director  
Regulatory Affairs

Food and Drug Administration  
Division of Dockets Management  
HFA-305  
5600 Fishers Lane  
Rockville, MD 20857

Dear Sirs:

**RE: Suitability Petition for Review and Action for a Generic Version of a  
Ceftiofur Hydrochloride Sterile Suspension**

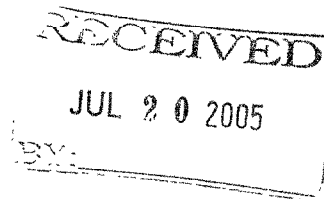
Pharmacia & Upjohn Company (P&U), a Division of Pfizer Inc, submitted a suitability petition for FDA review on 24 June 2005. This letter requested FDA's permission to submit an abbreviated new animal drug application (ANADA) for a generic version of EXCENEL® RTU, ceftiofur hydrochloride sterile suspension as approved under NADA 140-890. A copy of the letter is attached. P&U requests withdrawal of this petition without prejudice.

Please contact me at (269) 833-2482 if you have any questions on this submission.

Sincerely,

John W. Hallberg, D.V.M., Ph.D.

JWH/cs  
Enclosure



2005P-0277

WDL1



## Pfizer Animal Health

24 June 2005

**John W. Hallberg, D.V.M., Ph.D.**  
Associate Director  
Regulatory Affairs

Dr. John K. Harshman, Acting Staff Chief (HFV-104)  
FDA/Center for Veterinary Medicine  
Food and Drug Administration  
7500 Standish Place  
Rockville, MD 20855

Dear Dr. Harshman:

**RE: Suitability Petition for Review and Action for a Generic Version of a  
Ceftiofur Hydrochloride Sterile Suspension**

Pharmacia & Upjohn Company (P&U), a Division of Pfizer Inc. is submitting this suitability petition for FDA review and concurrence. P&U is requesting FDA's permission to submit an abbreviated new animal drug application (ANADA) for a generic version of EXCENEL® RTU, ceftiofur hydrochloride sterile suspension as approved under NADA 140-890. P&U is proposing one modification to the existing product label for EXCENEL RTU. P&U proposes to limit the route of injection to only the subcutaneous route of administration for cattle instead of both subcutaneous and intramuscular routes as approved for the pioneer product. The suitability petition is attached to this letter. P&U requests FDA's prompt approval of this petition.

Please contact me at (269) 833-2482 if you have any questions on this submission.

Sincerely,

A handwritten signature in black ink, appearing to read "John W. Hallberg", followed by a horizontal line.

John W. Hallberg, D.V.M., Ph.D

JWH/cs  
Attachments